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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,665	02/15/2001	Yiqun Wang	1001.1412101	2225

28075 7590 12/13/2004

CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER

ODLAND, KATHRYN P

ART UNIT PAPER NUMBER

3743

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/784,665	Applicant(s) WANG ET AL.	
	Examiner Kathryn Odland	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent-Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed November 9, 2004 have been fully considered but they are not persuasive.

Applicant argues, "More particularly, claims 1 and 9 both recite that the seal is (a) "releasably attached to the first port" and that the seal is (b) attached in a manner "so as to substantially prevent the passage of air into the lumen. First of all, it does not appear that the gasket, which the examiner has attempted to equate with the claimed seal, is releasably attached to the first port. McIntyre et al. is silent as to this point but the drawings indicate that the gasket 26 is an integral part of the housing 21." The examiner respectfully disagrees. The examiner has equated the gasket (26/28) with the seal. However, the examiner respectfully disagrees that the seal is integral. In looking at figure 4, for example, the seal (26/28) has crosshatches in a different direction than the housing (21). Thus, it does not appear from the figures that the seal (26/28) is integral with the housing. Rather, it appears that it is a separate element positioned in the housing. Further, the specification discusses that the gasket/seal would be made of materials such as rubber. It would not seem that it would be desirable to have the housing made of rubber. Also, column 5, lines 60-65 recite, "A second tubular, resilient gasket 28, positioned adjacent to the proximal side of the gasket 26...." This recitation discusses the positioning and placement of the gasket, further implying that it is not an integral component. Moreover, column 6, discusses compressing of the gasket in the

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housing and there is no implication in either the specification or the drawings that the gasket is integral with the housing. Thus, the gasket is considered releasable.

Applicant also argues, "Moreover, the gasket in McIntyre et al. cannot prevent the passage of air into the first lumen because, as Figure 4 clearly shows, side leg 22 independently provides an opening to the lumen." As discussed in the Office Action dated, January 23, 2004, although it is agreed that McIntyre et al. do indeed have a port member 20, column 7, lines 36-55 clearly disclose that "a three-way valve or stopcock (not shown) may be positioned between the syringe and the side leg." This additional seal would ensure/allow that the port to be closed and allowing the seal (via 26/28) to function as claimed and prevent air passage into the lumen that is in fluid communication with the inflatable member.

Further the combination of Gabel et al. with McIntyre et al. would not undermine the purpose of the catheter's distal end and render the catheter useless. It is asserted that it would be obvious to one with ordinary skill in the art to provide the system of McIntyre et al. with a pieceable seal, such as that of Gabel et al. Both McIntyre et al. and Gable et al. demonstrate seals that function to allow for purging. Therefore, modifying the seal of McIntyre et al. to be a pierceable seal is within the scope of the invention and in no way render the device useless. Additionally, both disclose the same elastomeric materials for the seal and the motivation to combine is stated in column 4 of Gable et al. Gable et al. discuss that a pierceable seal allows for the penetration and removal of cannula to be self-sealing after the cannula has been withdrawn.

Applicant has failed to provide structural limitations that define over the prior art of record. The rejection is reiterated below and this Office Action is made final.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIntyre et al. in US Patent No. 5,334,153 in view of Gabel et al. in US Patent No. 4,759,751.

Regarding claim 1, McIntyre et al. disclose a catheter assembly (generally 1) having a first tube having a proximal end, a distal end, and a first lumen (5) extending therethrough, wherein the lumen is in fluid communication with an expandable member (8) proximate the distal end of the first tube, as recited in column 5, lines 30-65 and seen in figures 1 and 4; a first port (such as at 20) on the proximal end of the first tube in fluid communication with the first lumen, as recited in columns 5 and 6; and a seal (26/28) releasably attached to the first port so as to substantially prevent the passage of air into the first lumen, wherein the first lumen has a pressure less than atmospheric pressure, as stated in column 2, lines 60-67 and column 7. This is further discussed in the office action dated January 23, 2004.

However, McIntyre et al. do not recite a pierceable seal. On the other hand, Gabel et al. disclose a pierceable seal (32) that provides the same function as that

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claimed. Gabel et al. state that the plug 32 is preferably an elastomeric material such as rubber so that it can be penetratable and self-sealing, in column 4, lines 56-62.

Further, Gabel et al. discuss solving the same problem of properly purging the lumen. Therefore, it would be obvious to one with ordinary skill in the art to provide the system of McIntyre et al. with a pierceable seal as taught by Gabel et al. for the purpose of purging the lumen properly as well as pre-purging the lumen.

Regarding claim 2, McIntyre et al. as modified recite that as applied to claim 1 as well as an expandable member is a balloon (8), as recited in column 4, line 14.

Regarding claims 3, 10 and 17, McIntyre et al. as modified recite that as applied to claims 1, 9 and 17 as well as a seal that is a polymer, as recited in column 5, lines 55-60 and column 6, lines 1-3. Further Gabel et al. teach a seal that is a polymer.

Therefore, it would be further obvious in the modification to have the seal be a polymer as taught by Gabel et al. for the purpose of a proper seal.

Regarding claims 4, 11 and 18, McIntyre et al. as modified recite that as applied to claims 1, 9 and 17. Further, Gabel et al. teach a seal that is rubber, as recited in column 4, lines 55-65. Therefore, it would be further obvious in the modification to have the seal be a rubber as taught by Gabel et al. for the purpose of a proper seal.

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Regarding claims 5, 12 and 19, McIntyre et al. as modified recite that as applied to claim 4, 11 and 18. Further, Gabel et al. teach a seal that is a self-sealing rubber septum, as recited in column 4, lines 55-65. Therefore, it would be further obvious in the modification to have the seal be a self-sealing rubber septum as taught by Gabel et al. for the purpose of a proper seal.

Regarding claim 6, 13 and 20, McIntyre et al. as modified recite that as applied to claim 1, 9 and 17. Applicant's claims 5, 12 and 19 require a self-sealing rubber septum. Gabel et al. teach a seal that is a self-sealing rubber septum, as recited in column 4, lines 55-65. Therefore, a seal that is plastic is considered an equivalent.

Regarding claims 7 14 and 21, McIntyre et al. as modified disclose that as applied to claims 1, 9 and 17. However, McIntyre et al. do not recite a first tube that includes a chemical coating capable of binding a quantity of CO.sub.2, N.sub.2, and O.sub.2. On the other hand, coatings are well known in the art and it would be obvious to one with ordinary skill in the art to modify the invention to include a coating that is capable of binding a quantity of CO.sub.2, N.sub.2, and O.sub.2 for the purpose of preventing escape of air and other gases, as discussed in column 1, lines 25-40.

Regarding claims 8, 15 and 21, McIntyre et al. as modified recite that as applied to claims 1, 9 and 17 as well as a catheter assembly that prior to use the first lumen is filled with a fluid, as recited in column 7.

Regarding claim 9, McIntyre et al. disclose a balloon catheter (1) with a proximal end and a distal end, having a first tube having a proximal end, a distal end, and a first lumen (5) extending therethrough, wherein the first tube includes a first port (generally at 20) on a proximal end thereof in fluid communication with the first lumen; a balloon (8) disposed at the distal end of the catheter and in fluid communication with the first lumen, as recited in columns 1 and 2; a seal (26/28) releasably attached to the first port so as to substantially prevent the passage of air into the first lumen wherein the first lumen is substantially free of air therein, as recited in column 5, lines 50-68 and column 6, lines 1-3. This is further discussed in the office action dated January 23, 2004.

However, McIntyre et al. do not recite a pierceable seal. On the other hand, Gabel et al. disclose a pierceable seal (32) that provides the same function as that claimed. Gabel et al. state that the plug 32 is preferably an elastomeric material such as rubber so that it can be penetratable and self-sealing, in column 4, lines 56-62. Further, Gabel et al. discuss solving the same problem of properly purging the lumen. Therefore, it would be obvious to one with ordinary skill in the art to provide the system of McIntyre et al. with a pierceable seal as taught by Gabel et al. for the purpose of purging the lumen properly as well as pre-purging the lumen.

Regarding claim 16, McIntyre et al recite a method of preparing a balloon catheter (1) via providing a balloon catheter including a first tube having a proximal end, a distal end, and a first lumen (5) extending therethrough, wherein the first tube has a

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first port (generally at 20) in fluid communication with the first lumen, and a seal (26/28) releasably attached to the first port so as to substantially prevent the passage of air into the first lumen with a balloon disposed proximate the distal end of the catheter in fluid communication with the first lumen, as recited in column 5; providing a sealing device that is detachably connectable to the first port, wherein the sealing device includes a seal detachably secured therein, as recited in column 5 and seen in figure 1; connecting the sealing device to the first port; using the sealing device to pull vacuum until the air pressure within the first lumen is substantially less than atmospheric pressure followed by placing the seal over the first port; and disconnecting the sealing device from the first port, as recited in column 2, lines 60-68, column 5, column 6, and column 7. This is further discussed in the office action dated January 23, 2004.

However, McIntyre et al. do not recite a pierceable seal. On the other hand, Gabel et al. disclose a pierceable seal (32) that provides the same function as that claimed. Gabel et al. state that the plug 32 is preferably an elastomeric material such as rubber so that it can be penetratable and self-sealing, in column 4, lines 56-62. Further, Gabel et al. discuss solving the same problem of properly purging the lumen. Therefore, it would be obvious to one with ordinary skill in the art to provide the system of McIntyre et al. with a pierceable seal as taught by Gabel et al. for the purpose of purging the lumen properly as well as pre-purging the lumen. Therefore, given this modification, the method would correspond accordingly.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (571) 272-4801. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



Heng Bennett
Supervisor Patent Examiner
Group 3700